

FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 6

Complete If Known

Application Number	10/736,990
Filing Date	December 17, 2003
First Named Inventor	Sprinkle, F. Murphy, Jr. et al.
Examiner Name	Not Yet Assigned
Attorney Dock Number	033018-150

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
MM	6,516,796		Kenneth A. Cox et al.	02-11-2003
	6,501,052		Kenneth A. Cox et al.	12-31-2002
	5,743,251		Tony M. Howell et al.	04-28-1998
	2,896,856		Kravits	07-28-1959
	3,084,698		Smith	04-09-1963
	3,157,179		Paullus et al.	11-17-1964
	3,162,324		Houser	12-22-1964
	3,431,393		Katsuda	04-04-1969
	3,486,663		Humphrey	12-30-1969
	3,658,059		Steil	04-25-1972
	3,716,416		Adlhart et al.	02-13-1973
	3,750,961		Franz	08-07-1973

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation	
					Yes	No
MM	667979	A	France	10-25-1929		
	354094	A	Belgium	09-1928		
	354004	A	Belgium	09-1928		
	94/09842	A	WIPO	05-11-1994		
	98/17131		WIPO	04-30-1998		
	0358114	A	Europe	03-14-1990		
	0642802	A2	Europe	05-14-1996		
	1036470	B1	Germany	08-14-1958		
	P953409		Hungary	06-03-1994		
	207457	A	Hungary	04-28-1993		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
MM	Barry, P.W. et al. "In Vitro Comparison of the Amount of Salbutamol Available for Inhalation From Different Formulations Used with Different Spacer Devices" Eur Respir J 1997; 10: 1345-1348
	Byron, Peter R. Ph.D., Chairman, "Recommendations of the USP Advisory Panel on Aerosols on the USP General Chapters on Aerosols (601) and Uniformity of Dosage Units (905)", Pharmacopeial Forum, Vol. 20, No. 3, pp. 7477-7505, May-June 1994 (023)
	Hindle, Michael et al., "High Efficiency Aerosol Production Using the Capillary Aerosol Generator" PharmSci 1998; 1: (1:suppl) S211
	Hindle, Michael et al., "High Efficiency Fine Particle Generation Using Novel Condensation Technology", Respiratory Drug Delivery VI (eds Dalby, R.N., Byron, P.R. & Farr, S.J.) Interpharm Press, Buffalo Grove, IL 1998 pp 97-102
	Hou, Shuguang et al. <i>Solution Stability of Budenonide in Novel Aerosol Formulations</i> Abstract No. 2582, Solid State Physical Pharmacy, November 17, 1998, p. S-307
	Kousaka, Yasuo et al., "Generation of Aerosol Particles by Boiling of Suspensions", Aerosol Science and Technology, 21:236-240 (1994) (023)

Examiner Signature



Date Considered

1/24/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Applicant Number	10/736,990	
			Filing Date	December 17, 2003	
			First Named Inventor	Sprinkel, F. Murphy, Jr. et al.	
			Examiner Name	Not Yet Assigned	
Sheet	2	of	6	Attorney Docket Number	033018-150

U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
Vmm	3,847,304		Cohen	11-12-1974
	3,859,398		Havstad	01-07-1975
	3,902,635		Jinotti	09-02-1975
	3,903,883		Pecina et al.	09-09-1975
	3,904,083		Little	09-09-1975
	3,967,001		Almaula et al.	06-29-1976
	3,987,941		Blessing	10-26-1976
	3,993,246		Erb et al.	11-23-1976
	4,042,153		Callahan et al.	08-16-1977
	4,060,082		Lindberg et al.	11-29-1977
	4,077,542		Pettersen	03-07-1978
	4,161,282		Erb et al.	07-17-1979
	4,162,501		Mitchell et al.	07-24-1979
	4,215,708		Bron	08-05-1980
	4,231,492		Rios	11-04-1980
	4,258,073		Payne	03-24-1981
	4,261,356		Turner et al.	04-14-1981
	4,289,003		Yang	09-15-1981
	4,291,838		Williams	09-29-1981
	4,303,083		Burruss, Jr.	12-01-1981
	4,383,171		Sinha et al.	05-10-1983
	4,391,308		Steiner	07-05-1983
	4,395,303		Weir	07-26-1983
	4,433,797		Galia	02-28-1984
	4,471,892		Coleman	09-18-1984
	4,512,341		Lester	04-23-1995
	4,575,609		Fassel et al.	03-11-1986
	4,627,432		Newell et al.	12-09-1986
	4,649,911		Knight et al.	03-17-1987
	4,682,010		Drapeau et al.	07-21-1987
	4,695,625		Macdonald	09-22-1987
	4,700,657		Butland	10-20-1987
	4,730,111		Vestal et al.	03-08-1988
	4,735,217		Gerth et al.	04-05-1988
	4,744,932		Browne	05-17-1988
	4,749,778		Fukuzawa et al.	06-07-1988
	4,762,995		Browner et al.	08-09-1988
	4,776,515		Michalchik	10-11-1998
	4,790,305		Zoltan et al.	12-13-1988
	4,811,731		Newell et al.	03-14-1989
	4,819,625		Howe	04-11-1989
	4,819,834		Thiel	04-11-1989
	4,829,996		Noakes et al.	05-16-1989
	4,837,260		Sato et al.	06-06-1989

Examiner Signature	<i>Michael Sprinkel</i>	Date Considered	1/24/05
--------------------	-------------------------	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Substitute for form 1449A/PTO & 1449B/PTO FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete If Known		
			Application Number	10/736,990	
			Filing Date	December 17, 2003	
			First Named Inventor	Sprinkel, F. Murphy, Jr. et al.	
			Examiner Name	Not Yet Assigned	
Sheet	3	of	6	Attorney Docket Number	033018-150

U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
hmr	4,848,374		Chard et al.	07-18-1989
	4,871,115		Hessey	10-03-1989
	4,871,623		Hoopman et al.	10-03-1989
	4,877,989		Drews et al.	10-31-1989
	4,911,157		Miller	03-27-1990
	4,922,901		Brooks et al.	05-08-1990
	4,926,852		Zoltan et al.	05-22-1990
	4,935,624		Henion et al.	06-19-1990
	4,941,483		Ridings et al.	07-17-1990
	4,947,875		Brooks et al.	08-14-1990
	4,974,754		Wirz	12-04-1990
	4,982,097		Slivon et al.	01-01-1991
	4,992,206		Waldron	02-12-1991
	5,021,802		Allred	06-04-1991
	5,044,565		Alexander	09-03-1991
	5,056,511		Ronge	10-15-1991
	5,060,671		Counts et al.	10-29-1991
	5,063,921		Howe	11-12-1991
	5,096,092		Devine	03-17-1992
	5,125,441		Mette	06-30-1992
	5,133,343		Johnson, IV et al.	07-28-1992
	5,134,993		van der Linden et al.	08-04-1992
	5,135,009		Müller et al.	08-04-1992
	5,144,962		Counts et al.	09-08-1992
	5,151,827		Ven et al.	09-29-1992
	5,178,305		Keller	01-12-1993
	5,184,776		Minier	02-09-1993
	5,217,004		Blasnik et al.	06-08-1993
	5,226,441		Dunmire et al.	07-13-1993
	5,228,444		Burch	07-20-1993
	5,230,445		Rusnak	07-27-1993
	5,231,983		Matson et al.	08-03-1993
	5,259,370		Howe	11-09-1993
	5,290,540		Prince et al.	03-01-1994
	5,298,744		Mimura et al.	03-29-1994
	5,299,565		Brown	04-05-1994
	5,322,057		Raabe et al.	06-21-1994
	5,327,915		Porenski et al.	07-12-1994
	5,342,180		Daoud	08-30-1994
	5,342,645		Eisele et al.	08-30-1994
	5,349,946		McComb	09-27-1994
	5,395,445		Bohanan	03-07-1995
	5,421,489		Holzner, Sr. et al.	06-06-1995
	5,462,597		Jubran	10-31-1995
	5,474,059		Cooper	12-12-1995

Examiner Signature	<i>Markus</i>	Date Considered	1/24/05
--------------------	---------------	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Substitute for form 1449A/PTO & 1449B/PTO			Complete if Known		
FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Application Number	10/736,990	
			Filing Date	December 17, 2003	
			First Named Inventor	Sprinkel, F. Murphy, Jr. et al.	
			Examiner Name	Not Yet Assigned	
Sheet	4	of	6	Attorney Dock # Number	033018-150


U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
MM	5,515,842		Ramseyer et al.	05-14-1996
	5,522,385		Lloyd et al.	06-04-1996
	5,556,964		Hofstra et al.	09-17-1996
	5,564,442		MacDonald et al.	10-15-1996
	5,565,677		Wexler	01-15-1996
	5,575,929		Yu et al.	11-19-1996
	5,585,045		Heinonen et al.	12-17-1996
	5,617,844		King	09-08-1997
	5,642,728		Andersson et al.	07-01-1997
	5,674,860		Carling et al.	10-07-1997
	5,682,874		Grabenkort et al.	11-04-1997
	5,730,158		Collins et al.	03-24-1998
	5,756,995		Maswadeh et al.	05-26-1998
	5,765,724		Amberg et al.	06-16-1998
	5,823,178		Lloyd et al.	10-20-1998
	5,839,430		Cama	11-24-1998
	5,855,202		Andrade	01-05-1999
	5,856,671		Henion et al.	01-05-1999
	5,863,652		Matsumura et al.	01-26-1999
	5,869,133		Anthony et al.	02-09-1999
	5,872,010		Karger et al.	02-16-1999
	5,878,752		Adams et al.	03-09-1999
	5,881,714		Yokoi et al.	03-16-1999
	5,906,202		Schuster et al.	05-25-1999
	5,914,122		Otterbeck et al.	06-22-1999
	5,932,249		Gruber et al.	08-03-1999
	5,932,315		Lum et al.	08-03-1999
	5,934,272		Lloyd et al.	08-10-1999
	5,934,273		Andersson et al.	08-10-1999
	5,944,025		Cook et al.	08-31-1999
	5,954,979		Counts et al.	09-21-1999
	5,957,124		Lloyd et al.	09-28-1999
	5,970,973		Gonda et al.	10-26-1999
	5,970,974		Van Der Linden et al.	10-26-1999
	5,978,548		Holmstrand et al.	11-02-1999
	5,993,633		Smith et al.	11-30-1999
	6,014,970		Ivri et al.	01-18-2000
	6,053,176		Adams et al.	04-25-2000
	6,054,032		Haddad et al.	04-25-2000
	6,069,214		McCormick et al.	05-30-2000
	6,069,219		McCormick et al.	05-30-2000
	6,070,575		Gonda et al.	06-06-2000
	6,071,428		Franks et al.	06-06-2000
	6,076,522		Dwivedi et al.	06-20-2000
	6,077,543		Gordon et al.	06-20-2000
	6,080,721		Patton	06-27-2000

Examiner Signature	<i>[Signature]</i>	Date Considered	1/24/05
--------------------	--------------------	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Substitute for form 1449A/PTO & 1449B/PTO FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/736,990	
			Filing Date	December 17, 2003	
			First Named Inventor	Sprinkel, F. Murphy, Jr. et al.	
			Examiner Name	Not Yet Assigned	
Sheet	5	of	6	Attorney Dock # Number	033018-150

U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
WV	6,085,740		Ivri et al.	06-11-2000
	6,085,753		Gonda et al.	07-11-2000
	6,089,228		Smith et al.	07-18-2000
	6,095,153		Kessler et al.	08-01-2000
	6,098,615		Lloyd et al.	08-08-2000
	6,098,620		Lloyd et al.	08-08-2000
	6,103,270		Johnson et al.	08-15-2000
	6,116,516		Ganan-Calvo	09-12-2000
	6,116,893		Peach	09-12-2000
	6,119,953		Ganan-Calvo et al.	09-19-2000
	6,123,068		Lloyd et al.	09-26-2000
	6,123,936		Platz et al.	09-26-2000
	6,131,567		Gonda et al.	10-17-2000
	6,131,570		Schuster et al.	10-17-2000
	6,136,346		Eljamal et al.	10-24-2000
	6,138,668		Patton et al.	10-31-2000
	6,155,268		Takeuchi	12-05-2000
	6,158,431		Poole	12-12-2000
	6,158,676		Hughes	12-12-2000
	6,159,188		Laibovitz et al.	12-12-2000
	6,164,630		Birdsell et al.	12-26-2000
	6,165,463		Platz et al.	12-26-2000
	6,167,880		Gonda et al.	01-02-2001
	6,174,469		Ganan-Calvo	01-16-2001
	6,182,712		Stout et al.	02-06-2001
	6,187,214		Ganan-Calvo	02-13-2001
	6,187,344		Eljamal et al.	02-13-2001
	6,189,803		Ganan-Calvo	02-20-2001
	6,192,882		Gonda	02-27-2001
	6,197,835		Ganan-Calvo	03-06-2001
	6,205,999		Ivri et al.	03-27-2001
	6,206,242		Amberg et al.	03-27-2001
	6,207,135		Rössling et al.	03-27-2001
	6,223,746		Jewett et al.	05-01-2001
	6,230,706		Gonda et al.	05-15-2001
	6,231,851		Platz et al.	05-15-2001
	6,234,167		Cox et al.	05-22-2001
	6,234,402		Ganan-calvo	05-22-2001
	6,235,177		Borland et al.	05-22-2001
	6,250,298		Gonda et al.	06-26-2001
	6,257,233		Burr et al.	07-10-2001
	6,258,341		Foster et al.	07-10-2001
	6,263,872		Schuster et al.	07-24-2001
	6,267,155		Parks et al.	07-31-2001

Examiner Signature		Date Considered	1/24/05
--------------------	---	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT


(use as many sheets as necessary)

Sheet 6 of 6


Complete if Known

Application Number	10/736,990
Filing Date	December 17, 2003
First Named Inventor	Sprinkel, F. Murphy, Jr. et al.
Examiner Name	Not Yet Assigned
Attorney Docket Number	033018-150


U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	6,275,650		Lambert	08-14-2001
	6,276,347		Hunt	08-21-2001
	6,284,525		Mathies et al.	09-04-2001
	6,288,360		Beste	09-11-2001
	6,290,685		Insley et al.	09-18-2001
	6,294,204		Rössling et al.	09-25-2001
	6,295,986		Patel et al.	10-02-2001
	6,318,361		Sosiak	11-20-2001
	2001/0032647	A1	Schuster et al.	10-25-2001
	6,196,219		Hess et al.	03-2001
	5,743,250		Gonda et al.	04-1998
	6,325,475		Hayes et al.	12-2001
	6,196,218		Voges	03-2001

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation	
					Yes	No
	168128	B	Hungary	11-28-1977		
	216121	B	Hungary	03-21-1991		
	923957	A1	EPO	6-23-1999		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Morén, Folke "Drug Deposition of Pressurized Inhalation Aerosols I. Influence of Actuator Tube Design" AB Draco (Subsidiary of AB Astra, Sweden) Research and Development Laboratories Pack, S-221 01 Lund (Sweden), International Journal of Pharmaceutics, 1 (1978) 205-212
	Newman, Stephen P. et al., "Deposition of Pressurized Suspension Aerosols Inhaled Through Extension Devices" ^{1-3rd} Am Rev Respir Dis 1981; 124:317-320
	Roth, G. et al. High Performance Liquid Chromatographic Determination of Epimers, Impurities, and Content of the Glucocorticoid Budesonide and Preparation of Primary Standard, Journal of Pharmaceutical Sciences, Vol. 69, No. 7, pp. 766-770, July 1980
	Notification of Transmittal of the International Search Report or the Declaration for PCT/US01/45749 dated October 3, 2002.
	Written Opinion for PCT/US01/45759 dated May 28, 2003
	Notification of Transmittal of International Preliminary Examination Report dated January 2, 2004 for PCT/US01/45759.

Examiner Signature



Date Considered

1/24/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.